

Clinical Data Management: Strategies for unregulated data

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ICH GCP

HIPAA

FDA

Clinical Trials



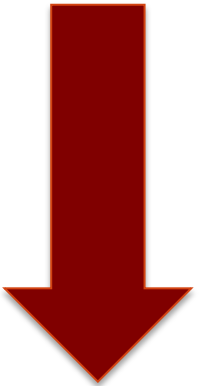
**Clinical Data
Management**

Regulation → Standard Practice

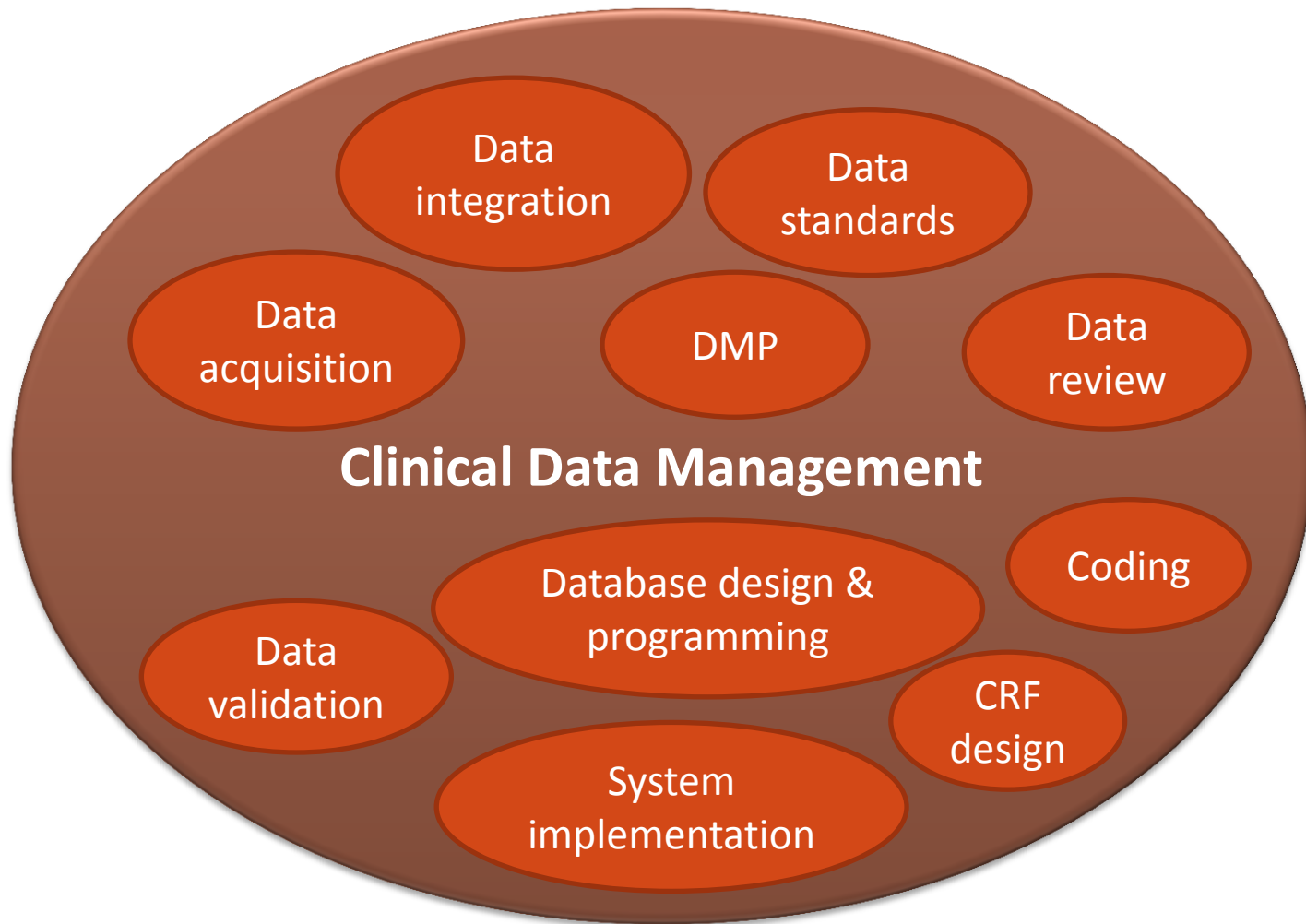
- Efficiency
- Efficacy*
- Safety*
- Accuracy
- Confidentiality/Privacy*



- Clear expectations
- Standards
- Best practices established



- Burdensome
- Inflexible
- Expensive



Good Clinical Data Management Practices

- 20 areas in 2011 document
- General themes
 - Plan, test, revise, test...implement
 - All stakeholders involved in design of protocol, data collection tools, data management plan, etc.
 - Document, document, document
 - Rule: the bigger the study (sites, data, people), the more planning you need

Good Clinical Data Management Practices

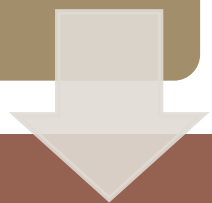
- Specify documents required for reproducible research
 - Organization: SOP
 - Study: Protocol, Manual of procedures, Data management plan, Statistical analysis plan
- Documentation serves practical purposes and benefits the team immediately
- Allows specification of roles and responsibilities from the beginning

Good Clinical Data Management Practices

Begin with the end in mind OR
Produce report-ready output



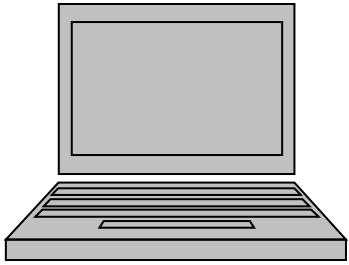
Collect data in a way that allows for
efficient data entry, processing,
validation, and analysis



Enabled by standardized data
collection tools (CRF)

Case Report Forms (CRF)

- Efficient (concise)
- Effective (clear)
- Minimize redundancy
- Minimize human error – consider completeness, accuracy, legibility, timeliness
- Enables fast data transfer across studies



Raw data



Processed data



Analysis

Centre No.

Subject No.

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Vital signs and physical measurements

Date of physical exam

DD	MMM	YYYY
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Physical exam

- ☐ Normal
☐ Abnormal - Not clinically significant
☐ Abnormal - Clinically significant → Specify abnormality in "Previous or current diseases" page 15

Height (cm)

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Weight (Kg)

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BSA (m²)

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Blood pressure

systolic				/				diastolic	mmHg
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Heart rate (beats/min)

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ECOG performance status

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EKG

Date of EKG

DD	MMM	YYYY
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Result

- ☐ Normal
☐ Abnormal - Not clinically significant
☐ Abnormal - Clinically significant → Specify in "Previous or current diseases" page 15

LVEF

Date of LVEF

DD	MMM	YYYY
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LVEF (patient value)

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Method of evaluation ☐ Echocardiogram ☐ MUGA scan

- ☐ Normal
☐ Abnormal - Not clinically significant
☐ Abnormal - Clinically significant → Specify in "Previous or current diseases" page 15

Symptomatic CHF

- ☐ No
☐ Yes → Specify below

NYHA classification

- ☐ Class I (asymptomatic, tick No for the question above)
☐ Class II
☐ Class III
☐ Class IV

Page

Reset Form

Print Form

I. This is for Health Department use. Uniquely identifying information is not transmitted to the Centers for Disease Control and Prevention.

Patient's name (last, first, MI)		Telephone number	Social Security Number	
Address (number, street)		City	County	State ZIP code

Date form complete Month Day Year	Report Status 1 New 2 Update	Report Source	Reporting health department	State patient number	City/county patient number
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Source code	Date of Birth (Month, Day, Year)	Gender 1 M 2 F	Current status 1 Alive 2 Dead 3 Unknown	CLIA number	Lab report/Accession number	Confidential C&T number
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III. Demographic Information	
Diagnosis status at report (check one) 1 HIV Infection (not AIDS) 2 AIDS	Age at Diagnosis Years
ETHNICITY 1 Hispanic 2 Not Hispanic nor Latino	RACE 1 American Indian/Alaskan Native 2 Native Hawaiian/Other Pacific Islander
Expanded race (specify):	
Check if HIV infection is presumed to have been acquired outside United States and Territories. Specify country:	
Residence at first diagnosis of HIV or AIDS: Homeless (Must use city/county/ZIP code of local health department (LHD) or facility of diagnosis.)	
City County State/Country ZIP code	
IV. Facility of Diagnosis	
Facility name City State/Country	
Facility setting (check one) 1 Public 2 Private	Facility type (check one) 01 Physician, HMO 20 Community Health Center 30 Counseling and Testing Site 31 Hospital, inpatient 32 Hospital, outpatient 99 Other (specify):

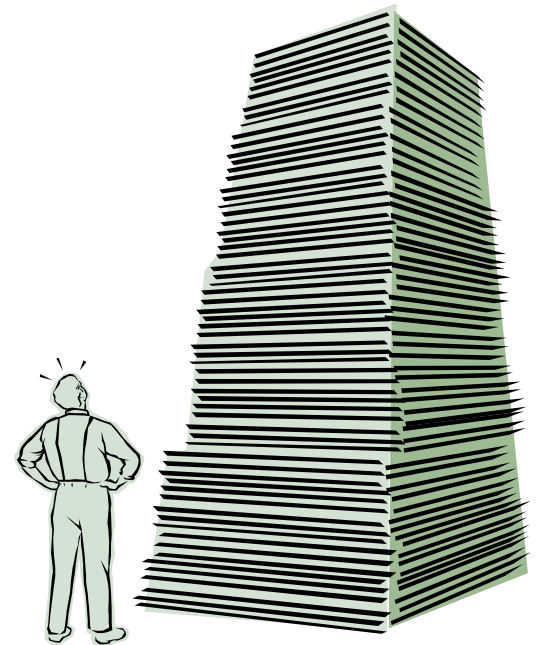
V. Patient Risk History (Check all that apply.)

Sex with a male	Yes	No	Unknown	Received clotting factor for hemophilia/coagulation disorder	Yes	No	Unknown	
Sex with a female	1	0	9	Specify disorder: 1 Factor VIII (Hemophilia A) 2 Factor IX (Hemophilia B) 8 Other (specify):	1	0	9	
Injected nonprescription drugs	1	0	9	Received transfusion of blood/components (other than clotting factor)	Month Year	Month Year	Yes No Unknown	
HETEROSEXUAL relations with any of the following:	Yes	No	Unknown	First: Last:	1	0	9	
Intravenous/injection drug user	1	0	9	Received transplant of tissue/organs or artificial insemination	1	0	9	
Bisexual male	1	0	9	Worked in a health care or clinical laboratory setting (Specify occupation):	1	0	9	
Person with hemophilia/coagulation disorder	1	0	9	Perinatally-acquired HIV infection regardless of year of birth	Yes No Unknown	1	0	9
Transfusion recipient with documented HIV infection	1	0	9	Other (specify):	1	0	9	
Transplant recipient with documented HIV infection	1	0	9					
Person with AIDS or documented HIV infection, risk not specified	Yes No Unknown	1	0	9				

VI. Laboratory Data (Indicate first documented test(s).)

A. HIV Antibody Test at Initial HIV/AIDS Diagnosis		Month Day Year	
HIV-1 EIA			
HIV-1/HIV-2 combination EIA			
Rapid HIV-1 EIA			
HIV-1 Western Blot/IFA			
Other HIV antibody test (Specify):			
B. Positive HIV Detection Test (Record earliest test.)		Month Day Year	
Culture <input type="checkbox"/> Antigen <input type="checkbox"/> DNA PCR <input type="checkbox"/> RNA PCR <input type="checkbox"/>			
Other (specify):			
Date of last documented negative HIV test		Month Day Year	
Specify facility type (use codes in Section IV):			
If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?		Yes No Unknown	
If yes, provide date of documentation by physician		Month Day Year	
C. HIV Viral Load Test (Record earliest test.)		Month Day Year	
Test type: Version:			
Other (specify type and version):			
Test result (Record in copies/mL and log10 values.)			
Detectable		Copies/mL: Log10: Greater than: Less than: copies/mL: copies/mL:	
Undetectable			
*Test type and version: 11=NuGene® HIV-1 QT (Organon/NASBA) 12=Amplivue HIV-1 Monitor® (Roche RT-PCR), version: 1.0 or 1.5 13=mpcr/Chiron BDR® (Roche RT-PCR), version: 2.0 or 3.0 14=Other (list name/manufacturer/version)			
D. Immunologic Lab Tests - At or closest to current diagnosis status			
CD4 count		cells/μl Month Day Year	
CD4 percent		% Month Day Year	
First <200 μl or <14%			
CD4 count		cells/μl Month Day Year	
CD4 percent		% Month Day Year	

Checklist + Form



**CRF + Instructions
= CRF Book**

Why do these strategies work?

- Save time and money
- Regulated environment – compliance is enforced
- Clinical trials are similar in structure and question are fairly narrow in scope

BUT!!!

- GCDMP provide practical strategies that meet regulatory requirements

References & Resources

1. Society for Clinical Data Management. (2011). Good Clinical Data Management Practices. Washington, D.C.
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3. Center for Cancer Research. (nd). Managing Data in Clinical Research. Retrieved from http://clinicaltrial.vc.ons.org/file_depot/0-10000000/0-10000/3367/folder/14779/Managing_Data_in_Clinical_Research.pdf
4. Howard, K. (2005). Data management in clinical trials. Retrieved from http://www.kestrelconsultants.com/reference_files/Operationalizing_the_Study.pdf